MAY. 9. 2005 3:40PM

Docket No. ECV-5587CON

## Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[ ] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

[X] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all énclosures are being sent via floatmile on the date indicated below to Facsimile No.

Dated:

May 9, 2005

Name of Person Certifying:

Printed Name:

Melissa Sanchez

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Michael Helmus

Assignee:

Edwards Lifesciences Corp.

Filing Date: April 2, 2004

Examiner:

Carlos A. Azpuru

Serial No.: 10/816,680

Group Art Unit: 1615

Title: DELIVERY SYSTEMS FOR PERIADVENTITIAL DELIVERY FOR TREATMENT

OF RESTENOSIS AND ANASTOMOTIC INTIMAL HYPERPLASIA

## TERMINAL DISCLAIMER UNDER 37 CFR §1.321(B)

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Petitioner, Edwards Lifesciences Corporation, a Delaware Corporation with its principal offices located at One Edwards Way, Irvine, in the County of Orange and State of California, represents that it is the assignee of the entire right, title and interest in and to the invention disclosed in the above-referenced U.S. Patent Application No. 10/816,680.

The above-referenced U.S. Patent Application No. 10/816,680 claims priority under 35 USC §120 back to U.S. Patent Application No. 09/771,480, now U.S. Pat. No. 6,730,313, which claims the benefit of the filing date of U.S. Provisional Patent Application No. 60/178,087.

All of the aforementioned patents and applications are commonly owned by Petitioner.

Petitioner represents that it is the assignee of the entire right, title and interest in and to the invention disclosed in U.S. Patent No. 6,730,313, and continuations thereof, by the following assignments/instruments:

Serial No.: 10/816,680

Docket No.: ECV-5587CON Amendment dated May 9, 2005

Responsive to Office Action of November 15, 2004

U.S. Patent No. 6,730,313 was assigned from the inventors to Edwards Lifesciences Corporation as shown by an Assignment recorded on August 13 at Reel 012070, Frame 0931 (recordation attached).

In accordance with 37 CFR 3.73, the undersigned certifies that the evidentiary documents with respect to ownership have been reviewed and that, to the best of the knowledge and belief of the undersigned, title is in the Petitioner seeking to take this action.

Petitioner hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application which would extend beyond the expiration date of prior U.S. Patent No. 6,730,313, whichever expiration date comes earlier.

Petitioner hereby agrees that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to prior U.S. Patent No. 6,730,313. This Agreement runs with any patent granted on the above-identified application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, Petitioner does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full statutory term as defined in 35 USC §§ 154 to 156 and 173 of prior U.S. Patent No. 6,730,313, as presently shortened by any terminal disclaimer, in the event that the prior U.S. Patent No. 6,730,313: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or

Serial No.: 10/816,680

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terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

## FEE PAYMENT

Please charge the necessary fee under 37 CFR §1.20(d) to Deposit Account No. 50-1225 (ECV-5587CON). A duplicate of this disclaimer is attached.

If there are any questions, please call the undersigned.

Dated: May 9, 2005

Respectfully submitted,

Edwards Lifesciences LLC

Rajiv Yadav, Ph.DUEsq. Registration No. 43,999

Edwards Lifesciences LLC

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